DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

State Food Safety Task Force Meetings; Availability of Conference Grants; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the anticipated availability of conference grant funds for the support of State Food Safety Task Force meetings contingent on the availability of fiscal year (FY) 2000 funds. This initiative is intended to support and encourage State food regulatory agencies to establish (or provide support of existing) regularly scheduled Food Safety Task Force meetings. These meetings should foster communication and cooperation within the State among State and local food safety regulatory agencies and is part of the President's Food Safety Initiative (FSI).

DATES: For States with existing State Food Safety Task Forces, the lead/champion/food regulatory agency must submit applications by March 24, 2000. For States in the process of developing a State Food Safety Task Force, submit applications by April 15, 2000. If the closing date falls on a weekend, or the date falls on a holiday, the date of submission will be extended to the following workday.

ADDRESSES: Application forms are available from, and completed applications should be submitted to Cynthia M. Polit, Grants Management Office, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301–827–7180, e-mail: cpolit@oc.fda.gov. Applications hand-carried or commercially delivered should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Regarding the administrative and financial management aspects of this notice: Cynthia M. Polit (address above).

Regarding the programmatic aspects of this notice: Paul M. Raynes, or Glenn E. Johnson, Division of Federal-State Relations (DFSR), Office of Regulatory Affairs (ORA), Food and Drug Administration (HFC–150), 5600 Fishers Lane, rm. 12–07, Rockville, MD 20857, 301–827–6906, or access the Internet at www.fda.gov/ora/fed__state/default.htm.

SUPPLEMENTARY INFORMATION: FDA will support meetings covered by this notice under section 1701 (300u-300u-5) of the Public Health Service (PHS) Act (42 U.S.C. 241) or the Radiation Control for Health and Safety Act of 1968 (Public Law 90–602) (42 U.S.C. 263b-n). FDA's Conference Grant Program is described in the Catalog of Federal Domestic Assistance, No. 93–103 and applicants are limited to State food safety regulatory agencies. Applications submitted under this program are subject to the requirements of Executive Order 12372. Requirements under the original FDA request for applications for its Conference Grant Program (52 FR 12257, April 15, 1987) apply. PHS strongly encourages all award recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

PHS urges applicants to submit workplans that address specific objectives of ''Healthy People 2000.'' Potential applicants may obtain a copy of ''Health People 2000'' (Full Report, stock No. 017–0010–0474–0) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, 202–512–1800.

I. Background

ORA is the inspection component of FDA and has 1,000 investigators and inspectors who cover the country's approximately 95,000 FDA-regulated businesses. These investigators and inspectors inspect more that 15,000 facilities a year. In addition to the standard inspection program, they conduct special investigations, food inspection recall audits, perform consumer complaint inspections and sample collections. FDA has relied on the States in assisting with the above duties through formal contracts, partnership agreements, and other informal arrangements. Under the FSI, the demands on both the agency and the States will increase. Procedures need to be reviewed and innovative changes made that increase effectiveness and efficiency and conserve resources. ORA will support FSI by: (1) Providing effective and efficient compliance of regulated products, and (2) providing high quality, science-based work that maximizes consumer protection.

Under the FSI, FDA is encouraging State food safety regulatory agencies to establish (or provide support of existing) regularly scheduled Food Safety Task Force meetings. These meetings should foster communication and cooperation within the State among State and local food safety regulatory agencies. The purpose of the meetings should be to discuss/resolve issues at the State and local level relating to: (1) State/local agency roles and responsibilities, (2) capacity and resource needs, (3) outbreak coordination and investigations, (4) information sharing and data collection, (5) uniform regulatory standards, (6) communications and education, (7) State/local laboratory operations and coordination, and (8) adoption/implementation of the Food Code.

II. Project Goals, Definitions, and Examples

The purpose of these meetings is to foster communication and cooperation within the State among State and local food safety regulatory agencies. The meetings should: (1) Provide a forum for all the stakeholders of the food safety initiative; (2) assist in adopting or implementing the Food Code; and (3) promote the integration of a Statewide food safety system to become a cost effective, efficient system to maximize the protection of the public health.

Grant funds will be awarded for 1 year for direct costs only to secure meeting facility rental/expenses and in-state travel expenses for meeting attendees during the 1-year period. FDA and the U.S. Department of Agriculture region/district representatives may be invited to be a non-member liaison or advisor at the meetings but the task force should develop its own guidelines for work, consensus decisionmaking, size, and format at the initial meeting. Conference grant funds may not be used for Federal employees to travel to these meetings.

DFSR will provide meeting guidelines and other meeting organization documents as requested. Information on ''Productive Meeting Fundamentals'' is available via the Fax-on-Demand system by calling 301–827–4352 and requesting document #1606. A model partnership agreement may be obtained from Fax-on-Demand by requesting document #1605. FDA encourages at least two meetings a year for these task forces and recommends one each quarter.

III. Reporting Requirements

A final Program Progress Report or conference proceedings and a final Financial Status Report (FSR) (SF–269) are required within 90 days of the expiration date of the project period as noted on the Notice of Grant Award. An original and two copies of each report shall be submitted to FDA's Grants Management Office. Failure to file these

reports in a timely fashion may jeopardize future grant support.

IV. Mechanism of Support

A. Award Instrument

Support for this program will be in the form of a grant. These grants will be subject to all policies and requirements that govern the conference grant programs of PHS, including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. The regulations issued under Executive Order 12372 also apply to this program and are implemented through the U.S. Department of Health and Human Services (DHHS) regulations at 45 CFR part 100. Executive Order 12372 sets up a system for State and local government review of applications for Federal financial assistance. Applicants (other than federally recognized Indian tribal governments) should contact the State's Single Point of Contact (SPOC) as early as possible to alert them to the prospective application(s) and to receive any necessary instructions on the State's review process. A current listing of SPOC's is included in the application kit. The SPOC should send any State review process recommendations to the FDA Grants Management Office (address above). The due date for the State process recommendations is no later than 60 days after the deadline date for the receipt of applications. FDA does not guarantee to accommodate or explain SPOC comments that are received after the 60-day cutoff.

B. Eligibility

These grants are available to State food regulatory agencies (see section IV.A of this document).

C. Length of Support

The length of support will be for 1 year from the date of issuance of the award.

V. Review Procedure and Criteria

All applications submitted in response to this RFA will first be reviewed by grants management and program staff for responsiveness. If applications are found to be nonresponsive, they will be returned to the applicant without further consideration.

Responsive applications will be reviewed and evaluated for scientific and technical merit by an ad hoc panel of experts in the subject field of the specific application. Final funding decisions will be made by the Commissioner of Food and Drugs or her designee.

Applicants are strongly encouraged to contact FDA to resolve any questions regarding criteria prior to the submission of their application. All questions of a technical or programmatic nature must be directed to the ORA Program Staff (address above) and all questions of an administrative or financial nature must be directed to the Grants Management Staff (address above). Applications will be given an overall score and judged based on all of the following criteria:

1. Participant determination of the size and membership of the meetings' operating rules and goals in relation to the mission and priorities of FDA;
2. Makeup of the participants to include State and local food safety agencies, industry, consumers, legislators (State and local) and other interested associations or groups. Recommended attendance at meetings is approximately 15 to 20 persons;
3. Information dissemination to constituents regarding the existence of the meetings and information regarding the goals and outcomes;
4. Biannual or quarterly meetings as necessary to accomplish the established goals;
5. Yearly self-evaluation concerning the progress toward achieving goals and outcomes.

VI. Submission Requirements

The original and two copies of the completed grant application Form PHS–5161–1 (Revised 5/96) for State and local governments should be delivered to the Grants Management Office (address above). The application receipt date is March 24, 2000, for applicants with an established task force and April 15, 2000, for applicants in the process of developing a task force. If the receipt date falls on a weekend or if the date falls on a holiday, the date of submission will be extended to the following workday. No supplemental material or addenda will be accepted after the receipt date.

The outside of the mailing package and item 2 of the application facepage should be labeled ''Response to RFA–FDA–ORA–00–1.''

Note: A lead/champion/initiating State food regulatory agency who will coordinate/host and take the lead in establishing the Food Safety Task Force must be determined within the State prior to submission of an application. That lead/champion/initiating State food regulatory agency would prepare and submit the application. Only one grant will be awarded per State. Approximately $250,000 will be available in FY 2000, subject to the availability of funds. FDA anticipates making awards, not to exceed $5,000 in direct costs per award. Support of these grants will be for 1 year. The number of grants funded will depend on the quality of the applications received and the availability of Federal funds to support the grant. These grants are available to State food regulatory agencies that have an existing State Food Safety Task Force as well as State food regulatory agencies that are in the process of developing a State Food Safety Task Force. The formation of these Food Safety Task Force meetings will not interfere with existing advisory mechanisms within the Federal/State/local system and is not a mandatory requirement of FDA.

VII. Method of Application

A. Submission Instructions

Applications will be accepted during working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt date. Applications will be considered received on time if sent or mailed on or before the receipt date as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.

Do not send applications to the Center for Scientific Research, National Institutes of Health (NIH). Any application that is sent to NIH, that is then forwarded to FDA and not received in time for orderly processing, will be deemed nonresponsive and returned to the applicant. Instructions for completing the application are included in Form PHS–5161–1. FDA is unable to receive applications via the Internet.

B. Format for Application

When using Form PHS 5161–1 (Revised 5/96), all instructions for the enclosed Standard Form 424 (SF424) should be followed using the nonconstruction application pages. The facepage of the application should be labeled ''RFA–FDA–ORA–00–1.''

Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on PHS Form 5161–1 were approved and issued under the Office of Management and Budget Circular A–102.

C. Legend

Unless disclosure is required by FOIA as amended (5 U.S.C. 552), as determined by the freedom of information officials of DHHS or by a court, data contained in the portions of an application that have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted and/or proprietary information shall not be used or disclosed except for evaluation purposes.

Dated: January 12, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–1539 Filed 1–21–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Allergenic Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Allergenic Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 10, 2000, 8:30 a.m. to 3:30 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: William Freas or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will receive an update on the organizational changes of the Laboratory of Immunobiochemistry, its regulatory activities (including reference replacements and lot release statistics) and its research activities. The committee will hear presentations and discuss the following regulatory issues: (1) Potency limits for standardized allergen vaccines, (2) selection of allergen extracts for standardization, and (3) a proposed algorithm for the standardization of new allergens.

Procedure: On February 10, 2000, from 8:30 a.m. to 3:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 26, 2000. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 3, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 11, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–1543 Filed 1–21–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0132]

FDA Modernization Act of 1997; Guidance on Medical Device Tracking; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the revised guidance document entitled ''Guidance on Medical Device Tracking.'' This guidance document, which replaces the previous guidance issued on February 12, 1999, provides guidelines to manufacturers and distributors concerning their responsibilities for medical device tracking under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Guidance on Medical Device Tracking'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments on ''Guidance on Medical Device Tracking'' to the contact person (address below). See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Chester T. Reynolds, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4618.

SUPPLEMENTARY INFORMATION:

I. Background

Section 211 of FDAMA (Public Law 105–115) amended the tracking provisions of section 519(e) of the act (21 U.S.C. 360i(e)) to authorize FDA, at its discretion, to issue orders that require a manufacturer to track a class II or class III device if: (1) The failure of the device would be reasonably likely to have serious adverse health consequences; (2) the device is intended to be implanted in the body for more than 1 year; or (3) the device is life sustaining or life supporting and used outside a device user facility. The FDAMA tracking provisions became effective on February 19, 1998.

The revised final guidance replaces the February 1999 guidance and clarifies the devices that must be tracked. Agency experience indicates that industry and other interested parties are confused about the term ''replacement heart valves'' because there is more than one type. The category of replacement heart valves that must be tracked is limited to mechanical heart valves only and does not include human allograft (tissue) heart valves. The revised guidance document includes this descriptive limitation.

Agency experience also indicates that industry and other interested parties are confused about which infusion pumps are subject to medical device tracking because the types of fluids the pumps are intended to deliver may not be clear from indications for use set out in labeling. The previous guidance stated that infusion pumps, except those designated and labeled for use